

Claims 63-68, 70-74, and 77 were rejected under 35 USC 102(b) as being anticipated by Kerc, WO 96/36318. The examiner commented as follows:

Kerc discloses a pharmaceutical composition comprising a core containing amorphous drug dispersed in dispersion polymer, and a coating surrounding the core (page 4, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs). The core further comprises surfactant, and water-soluble polymer such as polyvinylpyrrolidone (ID, and page 5, 2<sup>nd</sup> and 3<sup>rd</sup> paragraphs). Amorphous drug includes antibiotics, antihypertensives, antiparkinson, hypnotic, and those disclosed in page 5, 4<sup>th</sup> paragraph. Dispersion polymer includes hydroxypropylmethyl-cellulose (page 7, 1<sup>st</sup> paragraph). The composition can be prepared in granule (multiparticulate) form, and the granule can then be compressed into tablet (page 11, 5<sup>th</sup> paragraph, and examples).

The rejection is traversed on the basis that Kerc does not disclose all elements of Applicants' invention, particularly as reflected by the claims as now amended, hence by definition cannot anticipate. It is well accepted that the standard for anticipation is one of strict identity, meaning that for prior art to anticipate, it must contain all of the essential elements. Hybritech Inc. v. Monoclonal Antibodies, Inc. 231 USPQ 81 (Fed Cir 1986). See In re Donohue, 226 USPQ 619 (Fed Cir 1985) where it was stated:

an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device.

For purposes of the rejection over Kerc, Applicants note that their claims are directed to a controlled release osmotic dosage form, and that Kerc discloses nothing relating to osmotic devices. Rather, Kerc discloses a coated matrix delivery system comprising a core of drug-containing granules that also comprise a controlled release matrix, the core having a coating applied around it as a "third phase". Kerc does not disclose osmotic agents, nor does Kerc disclose that his dosage form should contain a delivery port of any type, both of which are required elements in Applicants' claims.

Further, both polymers listed as suitable for use in the coating (see Kerc at page 9) are enteric, meaning that they dissolve once the dosage form reaches the lower GI tract. Kerc himself describes his polymer film coating as being "...poorly soluble or gastro-resistant ...for additional delay in release", indicating its enteric nature. This is in contrast to Applicants, who require that their coating is non-dissolving and non-eroding during release of the drug. Since Kerc does not teach these elements of Applicants' claims (and in fact teaches a wholly different dosage form from Applicants) Kerc does not anticipate. Applicants' claims clearly support that their dosage form is different from Kerc, requires elements not disclosed by Kerc, and is accordingly not anticipated by Kerc. Withdrawal of the anticipation rejection over Kerc is accordingly respectfully requested.

Claims 49-57, 60-72, and 76-78 were rejected under 35 USC 103(a) over Kerc, in view of Wong, US 4,765,989. The Examiner relied upon Kerc for the reasons stated in making the §102 rejection. The examiner took the position, *inter alia*, that it would be obvious to modify Kerc to include at least one passageway in the coating as disclosed in Wong.

The rejection is traversed on the basis that it is based on hindsight, it being noted that the references are not properly combinable. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination." *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990); *See also ACS Hospital Systems, Inc. v. Montefiori Hospital*, 732 F.2d 1572, 1577 (Fed. Cir. 1984). The aforementioned case law is all the more applicable to the instant rejection where combining Wong with Kerc would defeat the purpose of Kerc.

As discussed above, Kerc uses a "gastro-resistant" coating that effects a delay in release. Kerc in fact repeatedly emphasizes that that his film coating effects delayed release in his dosage form with the gastro-resistant coating he employs. See, for example, Kerc at page 11, second full paragraph. Enteric coatings such as the one disclosed by Kerc are used to delay release in that they stay intact in the acid environment of the upper GI tract, but dissolve or otherwise come apart at the higher pH values encountered once the dosage form encounters the lower GI tract. Implementing a delivery port in an enteric coating such as the one required in Kerc would immediately expose Kerc's core to the GI environment, thereby defeating Kerc's purpose of delaying drug release. In different words, essentially the whole of Applicants' subparagraph (b) of claim 49 is missing from Kerc. Subparagraph (b) requires a delivery port and a water-permeable, non-dissolving and non-eroding coating around Applicants' core that controls the influx of water and that exposes Applicants' core to the GI tract without delay. Implementing such features in Kerc, such as the delivery port from Wong, is completely contrary to, and would defeat, the purpose (i.e., delayed release) expressly set forth in Kerc. Clearly one of ordinary skill in the art would not find it obvious to combine the Kerc and Wong references since they are at cross-purposes with respect to each other.

Claims 58, 59, and 73-75 were rejected under 35 USC 103(a) over Kerc, in view of Wong, and Kigoshi, US 6,254,889. The Examiner relied upon Kerc and Wong for the reasons previously stated in the Office Action. The Examiner appeared to be relying on Kigoshi for its teaching of particular dispersion polymers.

The rejection is traversed on the basis that Kigoshi is inadequate to fill in the gaps between Kerc and Wong, discussed above. Kerc discloses an enteric coating different from that required by Applicants in that it is not non-eroding and non-dissolving. Further, it would not be obvious to implement the delivery port of Wong in Kerc as that would defeat Kerc's purpose of a coating that delays release. Kigoshi simply discloses that some of the polymers useful as dispersion polymers in Applicants' invention are known. Kigoshi does not otherwise fill in any of the shortcomings of the Kerc/Wong combination, and the examiner has not otherwise provided

any basis as to how Kigoshi renders Applicants' claims obvious. It is accordingly respectfully submitted that the rejection of claims 58, 59, and 73-75 over Kerc, Wong and Kigoshi should be withdrawn.

In view of the foregoing comments and amendments, this case is believed to be in condition for allowance, and a Notice of Allowance is courteously solicited.

Respectfully submitted,

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